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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,911

09/05/2003

Arturo J. Angel

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07/25/2006

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/655,911

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 14-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 4 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of response to election/restriction dated 5-11-06 is acknowledged.

Claims 1 and 3-44 are pending.

The amendment submitted on 3-27-06, requesting the cancellation of claim 2 has been entered. In the last action (dated 4-12-06), examiner inadvertently stated that claims 1-44 are pending. However, upon entering the amendment of 3-27-06, claims 1 and 23-44 are pending.

Applicant's election with traverse of Group I, species I and sub-species 1, in the reply filed on 5-11-06 is acknowledged. The traversal is on the ground(s) that it does not pose a serious search burden on the examiner, that a search for art describing kits and compositions having capsaicin and capsaicin cleaning compositions will inevitably also encompass art describing methods for cleansing and methods for treating capsaicin-responsive conditions. This is not found persuasive because instant kit is not restricted to cleansing compositions comprising capsaicin and instead can include pain treating capsaicin composition or even compositions containing capsaicin as food additives and even extends to different types of compositions including patches. Further, art anticipating or rendering obvious a patch composition does not render obvious a non-patch composition. Therefore, it is a serious search burden to examine all the above groups, species and sub-species in patent and non-patent literature. If applicants declare equivalency between all the compositions, kits and solvents, then the examiner will examine all the groups. Therefore, the requirement is still deemed proper and is therefore made FINAL.

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Applicants acknowledged that claims 1, 3, 4 and 10-13 read on the elected species and sub-species. Therefore, claims 1, 3, 4 and 10-13 have been considered for examination and claims 5-9 and 14-44 have been withdrawn from consideration.

***Claim Rejections - 35 USC § 103***

Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,910,512 to Conant (Conant) by itself or Conant in view of US 6,403,589 to Meert et al (Meert).

Instant claims are directed to a kit comprising as separate components, a first composition comprising capsaicin or its analog and a second component comprising a substance in which capsaicin has a solubility of at least 10%.

Conant teaches a topical analgesic composition comprising capsaicin and/or capsaicin, for the treatment of pain and relief from arthritis (col. 1-2). Conant suggests a water-soluble capsaicin at a concentration of 0.1 to 1% (col. 2). Conant teaches water as an excellent for capsaicin and hence meets the claimed solubility suspending (at least 10% w/w). Conant teaches applying water-soluble capsaicin to the skin so that the epidermal layer is softened without harsh chemicals (col. 1, lines 57-60) and also teaches suspending the water-soluble capsaicin in hydrophilic bases before applying to the skin of patients to treat pain. Conant fails to teach the claimed kit having separate components. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to pack capsaicin and the solvent or the carrier for capsaicin separately and mix them before applying to skin because Conant teaches suspending water soluble capsaicin in various hydrophilic bases before

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applying to the skin for treating pain and therefore a skilled artisan would have expected capsaicin to be soluble in water and is therefore effective in treating pain, before applying.

Meert a method of treating chronic pain in warm-blooded animals with draflazine analogs having the structural formula I (col. 2, col. 7, lines 23-33). Meert teaches preparing the composition in various pharmaceutical forms and suggests employing solvents like water, glycols, oils, alcohols etc (col. 7, lines 47--65). Meert also teaches combining the draflazine with other analgesic compound such as NSAIDS, capsaicin analogues, NMDA receptor antagonists etc (col. 8, lines 47-60). Meert suggests administering additional analgesics either separately or sequentially or consecutively or concurrently with draflazine (col. 8, lines 65-67) for treating pain and using the preparation as a kit (col. 9, lines 1-20). While Meert does not specifically teach the combination of draflazine and capsaicin analog, Meert recognizes capsaicin analog for pain relief. Meert fails to teach the amount of capsaicin and the solvent for capsaicin as a separate component.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a kit comprising two components i.e., a first component comprising an effective amount of capsaicin (0.1% to 10% suggested by Conant) and a second component comprising draflazine and the solvents such as water because Meert suggests applying a combination of analgesics is advantageous because it helps in selecting the timing, sequence of administration and also requires a lower dose than


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when used individually. With respect to the claimed second component in which capsaicin has a solubility of at least 10%, the component (of Meert) containing drafalzine and water meets the requirement because water reads on the claimed solvent (also because Conant recognizes water as a solvent).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
July 20, 2006